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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,100 04/07/99 NARHI

L A-423C

U S PATENT OPERATIONS TDZ  
AMGEN INCORPORATION  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS CA 91320-1799

HM22/1205

EXAMINER

PRASAD, S

ART UNIT	PAPER NUMBER
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1646

8

DATE MAILED:

12/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/284,100

Applicant(s)

Narhi et al.

Examiner

Sarada C Prasad

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09/14/2000.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-8, 10-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8, 10-22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

**Detailed Action**

1. Claims 1-24 were originally filed.
2. Acknowledgement is made of Applicant's claim for foreign priority based on PCT/US97/18607 filed on 10/15/96 and the applicant's priority claims for provisional applications 60/028,493; 60/032,781 filed on 12/6/96; and 60/033,046 filed on 12/10/96 (Paper No. 7, dated 9/27/00).
3. Acknowledgement is made of Applicants' amendment (Paper No. 6, 09/14/2000) with cancellation of claims 1-5, 9, 23, 24; addition of claim 25; and amendment of claims 6-8, 10, 19 and 20.
4. Acknowledgement is made of Applicant's response to Restriction requirement (Paper No. 6, 9/14/2000). Claims 1-5, 9, and 23, 24 are cancelled. Claim 25 is added. Claims 6-8, 10, 19 and 20 have been amended. Original claims 11-18, 21-22; amended claims 6-8, 10, 19-20, and new claim 25 are under consideration.
5. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of each U.S. and foreign patent, each publication or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP 609 A(1) states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of

determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-8, 10-22, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 13, and 18 are vague and indefinite in reciting the term "optionally". It is unclear whether any of the limitations which follow the term "optionally" are required limitations, i.e. are the further steps of isolating said variant of KGF-2 are "optional" or critical. Therefore, the meats and bounds of these claims are unclear.

Claims 14, 15 and 22 are rejected insofar they are dependent on claims 13 and 18.

5b. Claim 25 recites the term KGF-2 as the variant of keratinocyte growth factor-2 which is indefinite language. The instant growth factor should be clearly stated the first time it is used instead of using the acronym in the claims.

Claims 6-8, 10-22 are rejected insofar as they depend on claim 25.

**Conclusion**

9. No claims are allowed.

Art Unit: 1646

**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.

Examiner

Art Unit 1646

October 12, 2000

*Prema Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**